

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Jenny LOUIE-HELM et al.

Divisional of Serial No.: 10/014,750

Group Art Unit: Unassigned

Filing Date: Filed Herewith

Examiner: Unassigned

Title: FORMULATION OF AN ERODIBLE, GASTRIC RETENTIVE ORAL DOSAGE FORM USING IN VITRO DISINTEGRATION TEST DATA

INFORMATION DISCLOSURE STATEMENT

Mail Stop Patent Application

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

This is an Information Disclosure Statement submitted for the Examiner's consideration.

Applicants respectfully request that the Examiner review and make of record the references identified below.

The references identified below were disclosed and/or cited in parent application Serial No. 10/014,750, filed October 25, 2001, and, as such, copies thereof are not included pursuant to the provisions of 37 CFR § 1.98(d).

PTO-1449 forms listing the references accompany this paper. Applicants would appreciate the Examiner's initialing and returning the forms to indicate that the references have been reviewed and made of record. The references are as follows:

U.S. PATENT DOCUMENTS		
Document No.	Issue Date / Publication Date	Patentee / Applicant
3,960,150	6/1/76	Hussain et al.
4,434,153	2/28/84	Urquhart et al.
4,690,824	9/1/87	Powell et al.
4,695,467	9/22/87	Uemura et al.
4,748,023	5/31/88	Tamás et al.
4,786,503	11/22/88	Edgren et al.
4,839,177	6/13/89	Colombo et al.
4,851,232	7/25/89	Urquhart et al.
4,865,849	9/12/89	Conte et al.
5,002,772	3/26/91	Curatolo et al.
5,007,790	4/16/91	Shell

U.S. PATENT DOCUMENTS		
Document No.	Issue Date / Publication Date	Patentee / Applicant
5,064,656	11/12/91	Gergely et al.
5,085,865	2/4/92	Nayak
5,213,808	5/25/93	Bar-Shalom et al.
5,232,704	8/3/93	Franz et al.
5,393,765	2/28/95	infeld et al.
5,422,123	6/6/95	Conte et al.
5,425,950	6/20/95	Dandiker et al.
5,487,901	1/30/96	Conte et al.
5,508,040	4/16/96	Chen
5,549,913	8/27/96	Colombo et al.
5,582,837	10/10/96	Shell
5,609,590	3/11/97	Herbig et al.
5,626,874	5/6/97	Conte et al.
5,635,210	6/3/97	Allen, Jr. et al.
5,650,169	7/22/97	Conte et al.
5,651,985	7/29/97	Penners et al.
5,681,583	10/28/97	Conte et al.
5,688,776	11/18/97	Bauer et al.
5,736,159	4/7/98	Chen et al.
5,738,874	4/14/98	Conte et al.
5,780,057	7/14/98	Conte et al.
5,783,212	7/21/98	Fassih et al.
5,811,126	9/22/98	Krishnamurthy
5,827,984	10/27/98	Sinnreich et al.
5,837,379	11/17/98	Chen et al.
5,840,329	11/24/98	Bai
5,840,332	11/24/98	Lerner et al.
5,861,173	1/19/99	Nishioka et al.
5,891,474	4/6/99	Busetti et al.
5,897,874	4/27/99	Stevens et al.
5,916,595	6/29/99	Chen et al.
5,945,125	8/31/99	Kim
5,972,389	10/26/99	Shell et al.
6,027,748	2/22/00	Conte et al.
6,033,685	3/7/00	Qiu et al.
6,066,337	5/23/00	Allen et al.
6,093,420	7/25/00	Baichwal
6,120,803	9/19/00	Wong et al.
6,174,497	1/16/01	Roinestad et al.
6,177,104	1/23/01	Allen et al.
6,187,337	2/13/01	Allen et al.
6,207,197	3/27/01	Illum et al.
6,221,395	4/24/01	Maggi et al.
6,261,601	7/17/01	Talwar et al.
6,340,475	01/22/02	Shell et al.

U.S. PATENT DOCUMENTS		
Document No.	Issue Date / Publication Date	Patentee / Applicant
6,368,628	4/9/02	Seth
6,451,808	9/17/02	Cowles
6,488,962	12/3/02	Berner et al.
2001/0018070	8/30/01	Shell et al.
Serial No. 09/425,491	Filed 10/22/99	Shell et al
Serial No. 10/029,134	Filed 10/25/01	Gusler et al.
Serial No. 10/045,823	Filed 11/6/01	Shell et al.
Serial No. 10/066,146	Filed 2/1/02	Lim et al.
Serial No. 10/152,914	Filed 5/20/02	Fara et al.
Serial No. 10/280,309	Filed 10/25/02	Berner et al.
Serial No. 10/280,852	Filed 10/25/02	Devane et al.

FOREIGN PATENT DOCUMENTS		
Document No.	Publication Date	Country
EP 0598309 B1	1/28/98	Europe
EP 0795324 A2	9/17/97	Europe
GB 1330829	9/19/73	United Kingdom
WO 96/32097 A1	10/17/96	PCT
WO 98/55107 A1	12/10/98	PCT
WO 00/23045 A1	4/27/00	PCT
WO 00/38650 A1	7/6/00	PCT
WO 01/32217 A3	5/10/01	PCT
WO 01/56544 A3	8/9/01	PCT
WO 01/97783 A1	12/27/01	PCT
WO 02/083687 A1	10/24/02	PCT

OTHER DOCUMENTS
ABRAHAMSSON et al. (1993), "Absorption, Gastrointestinal Transit, and Tablet Erosion of Felodipine Extended-Release (ER) Tablets," <i>Pharmaceutical Research</i> 10(5):709-714.
APICELLA et al. (1993), "Poly(ethylene oxide) (PEO) and Different Molecular Weight PEO Blends Monolithic Devices for Drug Release," <i>Biomaterials</i> 14(2):83-90.
BAUMGARTNER et al. (2000), "Optimisation of Floating Matrix Tablets and Evaluation of Their Gastric Residence Time," <i>International Journal of Pharmaceutics</i> 195:125-135.
BETTINI et al. (1994), "Swelling and Drug Release in Hydrogel Matrices: Polymer Viscosity and Matrix Porosity Effects," <i>European Journal of Pharmaceutical Sciences</i> 2:213-219.
CHEN et al. (2000), "Gastric Retention Properties of Superporous Hydrogel Composites," <i>Journal of Controlled Release</i> 64:39-51.
COLUMBO et al. (1990), "Drug Release Modulation by Physical Restrictions of Matrix Swelling," <i>International Journal of Pharmaceutics</i> 63:43-48.
DAVIS et al. (1986), "The Effect of Density on the Gastric Emptying of Single- and Multiple-Unit Dosage Forms," <i>Pharmaceutical Research</i> 3(4):208-213.
DESHPANDE et al. (1997), "Development of a Novel Controlled-Release System for Gastric Retention," <i>Pharmaceutical Research</i> 14(6):815-819.

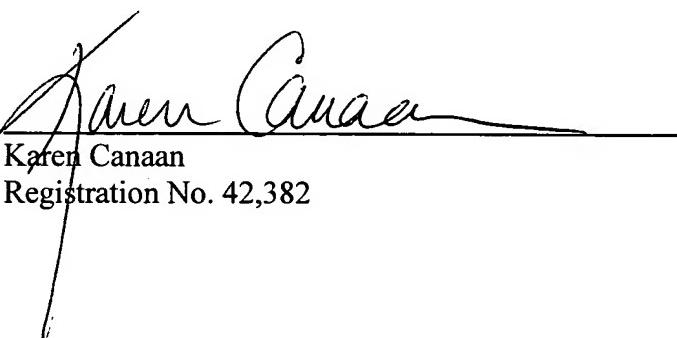
OTHER DOCUMENTS
FORD et al. (1987), "Importance of Drug Type, Tablet Shape and Added Diluents on Drug Release Kinetics from Hydroxypropylmethylcellulose Matrix Tablets," <i>International Journal of Pharmaceutics</i> 40:223-234.
GAO et al. (1996), "Swelling of Hydroxypropyl Methylcellulose Matrix Tablets. 2. Mechanistic Study of the Influence of Formulation Variables on Matrix Performance and Drug Release," <i>Journal of Pharmaceutical Sciences</i> 85(7):732-740.
HWANG et al. (1998), "Gastric Retentive Drug-Delivery Systems," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> 15(3):243-284.
JU et al. (1995), "Drug Release from Hydrophilic Matrices. 1. New Scaling Laws for Predicting Polymer and Drug Release Based on the Polymer Disentanglement Concentration and the Diffusion Layer," <i>Journal of Pharmaceutical Sciences</i> 84(12):1455-1463.
JU et al. (1995), "Drug Release from Hydrophilic Matrices. 2. A Mathematical Model Based on the Polymer Disentanglement Concentration and the Diffusion Layer," <i>Journal of Pharmaceutical Sciences</i> 84(12):1464-1477.
KANIWA et al. (1983), "The Bioavailability of Flufenamic Acid and Its Dissolution Rate from Capsules," <i>International Journal of Clinical Pharmacology, Therapy and Toxicology</i> 21(2):56-63.
KATORI et al. (1995), "Estimation of Agitation Intensity in the GI Tract in Humans and Dogs Based on <i>in Vitro/in Vivo</i> Correlation," <i>Pharmaceutical Research</i> 12(2):237-243.
KIM (1995), "Drug Release from Compressed Hydrophilic POLYOX-WSR Tablets," <i>Journal of Pharmaceutical Sciences</i> 84(3):303-306.
LAPIDUS et al. (1966), "Some Factors Affecting the Release of a Water-Soluble Drug from a Compressed Hydrophilic Matrix," <i>Journal of Pharmaceutical Sciences</i> 55(8):840-843.
LAPIDUS et al. (1968), "Drug Release from Compressed Hydrophilic Matrices," <i>Journal of Pharmaceutical Sciences</i> 57(8):1292-1301.
MAGGI et al. (2000), "High Molecular Weight Polyethylene Oxides (PEOs) as an Alternative to HPMC in Controlled Release Dosage Forms," <i>International Journal of Pharmaceutics</i> 195:229-238.
MAGGI et al. (2000), "Highly Swellable Multi-Layer Tablets to Prolong the Residence Time of the Delivery in the Stomach," <i>Journal of Controlled Release</i> 64:269-347.
OTH et al. (1992), "The Bilayer Floating Capsule: A Stomach-Directed Drug Delivery System for Misoprostol," <i>Pharmaceutical Research</i> 9(3):298-302.
RAO et al. (1988), "Swelling Controlled-Release Systems: Recent Developments and Applications," <i>International Journal of Pharmaceutics</i> 48:1-13.
REYNOLDS et al. (1998), "Polymer Erosion and Drug Release Characterization of Hydroxypropyl Methylcellulose Matrices" <i>Journal of Pharmaceutical Sciences</i> 87(9):1115-1123.
SHAMEEM et al. (1995), "Oral Solid Controlled Release Dosage Forms: Role of GI-Mechanical Destructive Forces and Colonic Release in Drug Absorption Under Fasted and Fed Conditions in Humans," <i>Pharmaceutical Research</i> 12(7):1049-1054.
SIEPMANN et al. (1999) "HPMC Matrices for Controlled Drug Delivery: A New Model Combining Diffusion, Swelling, and Dissolution Mechanisms and Predicting the Release Kinetics" <i>Pharmaceutical Research</i> 16(11):1748-1756.
YANG et al. (1996), "Zero-Order Release Kinetics from a Self-Correcting Floatable Asymmetric Configuration Drug Delivery System," <i>Journal of Pharmaceutical Sciences</i> 85(2):170-173.

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any of the above references constitutes prior art to the present application within the meaning of 35 USC § 102.

As this Information Disclosure Statement is being filed concurrently with the application, no fee is required.

Respectfully submitted,

By:


Karen Canaan
Registration No. 42,382

REED & EBERLE LLP
800 Menlo Avenue, Suite 210
Menlo Park, California 94025
(650) 330-0900 Telephone
(650) 330-0980 Facsimile

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(use as many sheets as necessary)

Sheet

1

of

4

Complete if Known

Application Number	Divisional of 10/014,750
Filing Date	Filed Herewith
First Named Inventor	Jenny LOUIE-HELM et al.
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	3100-0003.10

Attorney Docket Number

3100-0003.10

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document No.	Issue Date or Publication Date	Name of Patentee or Applicant of Cited Document	Class	Subclass	Filing Date if Appropriate
	AA	3,960,150	6/1/76	Hussain et al.			
	AB	4,434,153	2/28/84	Urquhart et al.			
	AC	4,690,824	9/1/87	Powell et al.			
	AD	4,695,467	9/22/87	Uemura et al.			
	AE	4,748,023	5/31/88	Tamás et al.			
	AF	4,786,503	11/22/88	Edgren et al.			
	AG	4,839,177	6/13/89	Colombo et al.			
	AH	4,851,232	7/25/89	Urquhart et al.			
	AI	4,865,849	9/12/89	Conte et al.			
	AJ	5,002,772	3/26/91	Curatolo et al.			
	AK	5,007,790	4/16/91	Shell			
	AL	5,064,656	11/12/91	Gergely et al.			
	AM	5,085,865	2/4/92	Nayak			
	AN	5,213,808	5/25/93	Bar-Shalom et al.			
	AO	5,232,704	8/3/93	Franz et al.			
	AP	5,393,765	2/28/95	infeld et al.			
	AQ	5,422,123	6/6/95	Conte et al.			
	AR	5,425,950	6/20/95	Dandiker et al.			
	AS	5,487,901	1/30/96	Conte et al.			
	AT	5,508,040	4/16/96	Chen			
	AU	5,549,913	8/27/96	Colombo et al.			
	AV	5,582,837	10/10/96	Shell			
	AW	5,609,590	3/11/97	Herbig et al.			
	AX	5,626,874	5/6/97	Conte et al.			
	AY	5,635,210	6/3/97	Allen, Jr. et al.			
	AZ	5,650,169	7/22/97	Conte et al.			
	BA	5,651,985	7/29/97	Penners et al.			
	BB	5,681,583	10/28/97	Conte et al.			
	BC	5,688,776	11/18/97	Bauer et al.			
	BD	5,736,159	4/7/98	Chen et al.			
	BE	5,738,874	4/14/98	Conte et al.			
	BF	5,780,057	7/14/98	Conte et al.			
	BG	5,783,212	7/21/98	Fassihi et al.			
	BH	5,811,126	9/22/98	Krishnamurthy			
	BI	5,827,984	10/27/98	Sinnreich et al.			
	BJ	5,837,379	11/17/98	Chen et al.			
	BK	5,840,329	11/24/98	Bai			
	BL	5,840,332	11/24/98	Lerner et al.			
	BM	5,861,173	1/19/99	Nishioka et al.			
	BN	5,891,474	4/6/99	Busetti et al.			
	BO	5,897,874	4/27/99	Stevens et al.			
	BP	5,916,595	6/29/99	Chen et al.			
	BQ	5,945,125	8/31/99	Kim			

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(use as many sheets as necessary)

Sheet	2	of	4	Attorney Docket Number	3100-0003.10
-------	---	----	---	------------------------	--------------

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document No.	Issue Date or Publication Date	Name of Patentee or Applicant of Cited Document	Class	Subclass	Filing Date if Appropriate
	BR	5,972,389	10/26/99	Shell et al.			
	BS	6,027,748	2/22/00	Conte et al.			
	BT	6,033,685	3/7/00	Qiu et al.			
	BU	6,066,337	5/23/00	Allen et al.			
	BV	6,093,420	7/25/00	Baichwal			
	BW	6,120,803	9/19/00	Wong et al.			
	BX	6,174,497	1/16/01	Roinestad et al.			
	BY	6,177,104	1/23/01	Allen et al.			
	BZ	6,187,337	2/13/01	Allen et al.			
	CA	6,207,197	3/27/01	Illum et al.			
	CB	6,221,395	4/24/01	Maggi et al.			
	CC	6,261,601	7/17/01	Talwar et al.			
	CD	6,340,475	01/22/02	Shell et al.			
	CE	6,368,628	4/9/02	Seth			
	CF	6,451,808	9/17/02	Cowles			
	CG	6,488,962	12/3/02	Berner et al.			
	CH	2001/0018070	8/30/01	Shell et al.			
	CI	Serial No. 09/425,491	10/22/99	Shell et al.			10/22/99
	CJ	Serial No. 10/029,134	10/25/01	Gusler et al.			10/25/01
	CK	Serial No. 10/045,823	11/6/01	Shell et al.			11/6/01
	CL	Serial No. 10/066,146	2/1/02	Lim et al.			2/1/02
	CM	Serial No. 10/152,914	5/20/02	Fara et al.			5/20/02
	CN	Serial No. 10/280,309	10/25/02	Berner et al.			10/25/02
	CO	Serial No. 10/280,852	10/25/02	Devane et al.			10/25/02

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document No.	Publication Date	Country	Class	Subclass	T
	CP	EP 0598309 B1	1/28/98	Europe			
	CQ	EP 0795324 A2	9/17/97	Europe			
	CR	GB 1330829	9/19/73	United Kingdom			
	CS	WO 96/32097 A1	10/17/96	PCT			
	CT	WO 98/55107 A1	12/10/98	PCT			
	CU	WO 00/23045 A1	4/27/00	PCT			
	CV	WO 00/38650 A1	7/6/00	PCT			
	CW	WO 01/32217 A3	5/10/01	PCT			
	CX	WO 01/56544 A3	8/9/01	PCT			
	CY	WO 01/97783 A1	12/27/01	PCT			
	CZ	WO 02/083687 A1	10/24/02	PCT			

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(use as many sheets as necessary)

Sheet

3

of

4

Complete if Known

Application Number	Divisional of 10/014,750
Filing Date	Filed Herewith
First Named Inventor	Jenny LOUIE-HELM et al.
Art Unit	Unassigned
Examiner Name	Unassigned

Attorney Docket Number

3100-0003.10

OTHER DOCUMENTS — NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), Title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	DA	ABRAHAMSSON et al. (1993), "Absorption, Gastrointestinal Transit, and Tablet Erosion of Felodipine Extended-Release (ER) Tablets," <i>Pharmaceutical Research</i> 10(5):709-714.	
	DB	APICELLA et al. (1993), "Poly(ethylene oxide) (PEO) and Different Molecular Weight PEO Blends Monolithic Devices for Drug Release," <i>Biomaterials</i> 14(2):83-90.	
	DC	BAUMGARTNER et al. (2000), "Optimisation of Floating Matrix Tablets and Evaluation of Their Gastric Residence Time," <i>International Journal of Pharmaceutics</i> 195:125-135.	
	DD	BETTINI et al. (1994), "Swelling and Drug Release in Hydrogel Matrices: Polymer Viscosity and Matrix Porosity Effects," <i>European Journal of Pharmaceutical Sciences</i> 2:213-219.	
	DE	CHEN et al. (2000), "Gastric Retention Properties of Superporous Hydrogel Composites," <i>Journal of Controlled Release</i> 64:39-51.	
	DF	COLUMBO et al. (1990), "Drug Release Modulation by Physical Restrictions of Matrix Swelling," <i>International Journal of Pharmaceutics</i> 63:43-48.	
	DG	DAVIS et al. (1986), "The Effect of Density on the Gastric Emptying of Single- and Multiple-Unit Dosage Forms," <i>Pharmaceutical Research</i> 3(4):208-213.	
	DH	DESHPANDE et al. (1997), "Development of a Novel Controlled-Release System for Gastric Retention," <i>Pharmaceutical Research</i> 14(6):815-819.	
	DI	FORD et al. (1987), "Importance of Drug Type, Tablet Shape and Added Diluents on Drug Release Kinetics from Hydroxypropylmethylcellulose Matrix Tablets," <i>International Journal of Pharmaceutics</i> 40:223-234.	
	DJ	GAO et al. (1996), "Swelling of Hydroxypropyl Methylcellulose Matrix Tablets. 2. Mechanistic Study of the Influence of Formulation Variables on Matrix Performance and Drug Release," <i>Journal of Pharmaceutical Sciences</i> 85(7):732-740.	
	DK	HWANG et al. (1998), "Gastric Retentive Drug-Delivery Systems," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> 15(3):243-284.	
	DL	JU et al. (1995), "Drug Release from Hydrophilic Matrices. 1. New Scaling Laws for Predicting Polymer and Drug Release Based on the Polymer Disentanglement Concentration and the Diffusion Layer," <i>Journal of Pharmaceutical Sciences</i> 84(12):1455-1463.	
	DM	JU et al. (1995), "Drug Release from Hydrophilic Matrices. 2. A Mathematical Model Based on the Polymer Disentanglement Concentration and the Diffusion Layer," <i>Journal of Pharmaceutical Sciences</i> 84(12):1464-1477.	
	DN	KANIWA et al. (1983), "The Bioavailability of Flufenamic Acid and Its Dissolution Rate from Capsules," <i>International Journal of Clinical Pharmacology, Therapy and Toxicology</i> 21(2):56-63.	
	DO	KATORI et al. (1995), "Estimation of Agitation Intensity in the GI Tract in Humans and Dogs Based on <i>in Vitro/in Vivo</i> Correlation," <i>Pharmaceutical Research</i> 12(2):237-243.	
	DP	KIM (1995), "Drug Release from Compressed Hydrophilic POLYOX-WSR Tablets," <i>Journal of Pharmaceutical Sciences</i> 84(3):303-306.	
	DQ	LAPIDUS et al. (1966), "Some Factors Affecting the Release of a Water-Soluble Drug from a Compressed Hydrophilic Matrix," <i>Journal of Pharmaceutical Sciences</i> 55(8):840-843.	
	DR	LAPIDUS et al. (1968), "Drug Release from Compressed Hydrophilic Matrices," <i>Journal of Pharmaceutical Sciences</i> 57(8):1292-1301.	
	DS	MAGGI et al. (2000), "High Molecular Weight Polyethylene Oxides (PEOs) as an Alternative to HPMC in Controlled Release Dosage Forms," <i>International Journal of Pharmaceutics</i> 195:229-238.	
	DT	MAGGI et al. (2000), "Highly Swellable Multi-Layer Tablets to Prolong the Residence Time of the Delivery in the Stomach," <i>Journal of Controlled Release</i> 64:269-347.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(use as many sheets as necessary)

Sheet

4

of

4

Complete if Known

Application Number	Divisional of 10/014,750
Filing Date	Filed Herewith
First Named Inventor	Jenny LOUIE-HELM et al.
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	3100-0003.10

OTHER DOCUMENTS — NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), Title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	DU	OTH et al. (1992), "The Bilayer Floating Capsule: A Stomach-Directed Drug Delivery System for Misoprostol," <i>Pharmaceutical Research</i> 9(3):298-302.	
	DV	RAO et al. (1988), "Swelling Controlled-Release Systems: Recent Developments and Applications," <i>International Journal of Pharmaceutics</i> 48:1-13.	
	DW	REYNOLDS et al. (1998), "Polymer Erosion and Drug Release Characterization of Hydroxypropyl Methylcellulose Matrices" <i>Journal of Pharmaceutical Sciences</i> 87(9):1115-1123.	
	DX	SHAMEEM et al. (1995), "Oral Solid Controlled Release Dosage Forms: Role of GI-Mechanical Destructive Forces and Colonic Release in Drug Absorption Under Fasted and Fed Conditions in Humans," <i>Pharmaceutical Research</i> 12(7):1049-1054.	
	DY	SIEPMANN et al. (1999) "HPMC Matrices for Controlled Drug Delivery: A New Model Combining Diffusion, Swelling, and Dissolution Mechanisms and Predicting the Release Kinetics" <i>Pharmaceutical Research</i> 16(11):1748-1756.	
	DZ	YANG et al. (1996), "Zero-Order Release Kinetics from a Self-Correcting Floatable Asymmetric Configuration Drug Delivery System," <i>Journal of Pharmaceutical Sciences</i> 85(2):170-173.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.